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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/301,766	04/29/1999	EIJIRO WATANABE	0020-4559P	6045

2292 7590 02/06/2002

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EXAMINER

KRUSE, DAVID H

ART UNIT PAPER NUMBER

1638

DATE MAILED: 02/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/301,766

Examiner

David H Kruse

Applicant(s)

WATANABE ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10, 16-23 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 16-23 and 28-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14&15. 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statements filed 1 March 2001 and 2 March 2001 have been considered.

### ***Status of the Specification***

2. The terminal disclaimer filed on 9 November 2000 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted which issues from co-pending Application No. 08/922,914 has been reviewed and is accepted. The terminal disclaimer has been recorded as Paper No. 12.
3. The rejection of claims 1-10 and 16-23 as provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-4, 6-18, 30-36, 40-41 and 43-44 of copending Application No. 08/992,914 is withdrawn in view of the Terminal Disclaimer filed 9 November 2000.
4. The rejection of claims 1-10 and 16 under 35 U.S.C. § 101 as directed to non-statutory subject matter is withdrawn in view of Applicant's amendments to the claims.
5. The rejection of claims 1 and 16-23 under 35 U.S.C. § 112, first paragraph, for scope of enablement is withdrawn.
6. The rejection of claims 1-10, 16, 18, 19 and 22 under 35 U.S.C. § 102(b) as being anticipated by Castillo *et al* 1990 is withdrawn in view of Applicant's arguments.
7. Those rejections not specifically addressed in this Office Action are withdrawn.

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8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Specification***

9. The disclosure is objected to because of the following informalities: At page 23, the structure of the "Coding Table" is confusing and should be labeled as -- Table 1 --. A revised, more clearly structured and labeled table is required in order to prevent confusion in printing at the time of allowance of the instant Application.

Appropriate correction is required.

***Claim Rejections - 35 USC § 101/112***

10. Claims 1-10, 16-23 and 28-30 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The specification discloses nucleic acid sequences that encode putative raffinose synthase enzymes (SEQ ID Nos. 2, 4, 6 and 8). The specification asserts that these nucleic acid sequences encode raffinose synthase (page 8 of the Specification). However, Applicant has provided no evidence to suggest that the encoded proteins function as raffinose synthase. There are no working examples to demonstrate what specifically the encoded polypeptides will be exhibited upon expression in a transgenic plant cell. Applicant has only provided examples of transforming a plant with a nucleic acid that encodes a putative raffinose synthase enzyme, but provides no evidence of function in the transformed plant (see for example, Example 9 on pages 49-51 of the

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specification). Consequently, Applicant has not defined a specific and substantial utility for the claimed nucleic acids, hence, a well-established utility is not known.

Claims 1-10, 16-23 and 28-30 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The art teaches that ultimately the function of any DNA sequence, whose identity is based solely on homology, can only be proved by experiments designated to evaluate that function (see Duggleby 1997, Gene 190:245-249, in particular page 248, left column, last paragraph).

***Claim Rejections - 35 USC § 112***

Claims 1, 16-23 and 28-30 rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is modified from that set forth in the last Office Action mailed 10 May 2000. Applicant's arguments filed 9 November 2000 have been fully considered but they are not persuasive.

Applicant argues that Applicants have recited common functional characteristics to sufficiently define the generic subject matter, specifically the specification indicates a method of isolating other plant raffinose synthase genes (pages 12 and 13 of the Remarks).

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The Examiner responds that Applicant has only described specifically nucleotide sequences from *Glycine max* (SEQ ID NO: 2), *Beta vulgaris* (SEQ ID NO: 4), *Brassica juncea* (SEQ ID NO: 6) and *Brassica napus* (SEQ ID NO: 8). Applicant has not described specific molecular features that describe the genus of plant raffinose synthase-encoding genes, only a functional characteristic that would be common to all plant raffinose synthase-encoding genes. Applicant's description of a method of identifying other plant raffinose synthase-encoding genes does not constitute an adequate written description of all plant raffinose synthase-encoding genes. See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. *The instantly claimed genus is very broad, given the low stringency conditions in claim 1.*

**Claim Rejections - 35 USC § 102**

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. § 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. § 122(b). Therefore, this application is examined under 35 U.S.C. § 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

12. Claims 1, 16-22, 28, 29 and 30 are rejected under 35 U.S.C. § 102(e) as being anticipated by Osumi *et al* (U.S. Patent 6,166,292), filed April 1997.

Osumi discloses a nucleic acid isolated from a dicot, cucumber, that encodes a raffinose synthase enzyme (see claim 1) and an isolated DNA which originates from an organism having an ability to produce raffinose from sucrose and galactinol which is hybridizable under "a stringent condition" with said nucleic acid (see claim 2(b)). The isolated nucleic acids of Applicant's claim 1 would inherently be hybridizable under a *low or moderately* stringent condition to the coding region of Osumi's SEQ ID NO:4. Osumi discloses a chimeric gene, plasmid, transformed microorganism and transformed plant comprising said isolated nucleic acid (see columns 22-24). Hence, Osumi has previously disclosed all of the claim limitations.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claim 23 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Osumi *et al* (U.S. Patent 6,166,292).

The teachings of Osumi are discussed above.

Osumi does not specifically teach a method for producing a raffinose synthase comprising collecting the raffinose synthase from a transformant.

It would have been *prima face* obvious to one of ordinary skill in the art at the time of Applicants' invention to isolate the expressed recombinant raffinose synthase as taught by Osumi in Example 4 at columns 23-24. Osumi clearly teaches a method of isolating the native raffinose synthase enzyme from cucumber in Example 1 at columns 16-18. Given the teachings of Osumi, one of ordinary skill in the art would have had a reasonable expectation of success in isolating the recombinant raffinose synthase as taught by Osumi using the isolation method taught by same.

#### ***Double Patenting***

15. Claims 1, 16-23 and 28-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-7, 13-17 and 21 of copending Application No. 09/612,095. Although the conflicting claims are not identical, they are not patentably distinct from each other because the "isolated" DNAs and methods of the copending application would be encompassed by the claims of the instant application, in particular Claim 1 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 1-3, 16-23 and 28-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 44-49, 54, 55 and 58 of copending Application No. 09/415,918. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to a nucleic acid encoding a raffinose synthase



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isolated from *Glycine max* or a nucleic acid encoding a raffinose synthase that will hybridize thereto and methods of using same.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Conclusion**

17. Claims 2-10 appear to be free of the prior art because there is no disclosure or suggestion of the specific <sup>isolated</sup> nucleotide sequences or polypeptides encoded by same.

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Kim Davis whose telephone number is (703) 305-3015.

David H. Kruse, Ph.D.  
30 January 2002

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP ~~180~~ 1638

